

REMARKS

The Amendments

The claims are amended to address the claim objections and 35 U.S.C. §112, second paragraph, rejection. Further, the claims are amended to correct non-substantive formalities and put the claims in a form more customary to US practice. The amendments do not narrow the scope of the claims and/or were not made for reasons related to patentability. The amendments should not be interpreted as acquiescence to any objection or rejection made in this application.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Restriction Requirement

Applicants maintain their traversal of the restriction requirement. Although salbutamol can be used to treat COPD, there is no basis to conclude that such a process is materially the same as applicants' process with different compounds. Since distinct compounds almost always have distinct properties, one of ordinary skill in the art would expect that carrying out the process with salbutamol would provide a different result from applicants' invention. In fact, the Barnes reference of record makes clear that tiotropium bromide has significantly different properties than other bronchodilators and treatment thereof provides a different and advantageous result. Thus, the restriction requirement should be withdrawn, in total. Applicants also reiterate that, if the restriction is maintained, the method claims here would be subject to rejoinder.

The Claim Objections

The claim objections are rendered moot by the above amendments.

The Rejection under 35 U.S.C. §112, second paragraph

The rejection of claims 1-10 and 20-34 under 35 U.S.C. §112, second paragraph, is believed to be rendered moot by the above amendments.

The Rejection under 35 U.S.C. §112, first paragraph

The rejection of claims 1-6, 9, 20-23, 29-30 and 34 under 35 U.S.C. §112, first paragraph, for lack of written description, is believed to be rendered moot by the above amendment. The claims clarify that the hydrates and solvates are separate embodiments in the Markush group, not a “dual activity” group.

The Rejection under 35 U.S.C. §103

The rejection of claims 1-10 and 20-34 under 35 U.S.C. §103, as being obvious over Duplantier (U.S. Patent No. 6,004,974) in view of Barnes (Am.J.Respir.Crit.Care Med., 1999), is respectfully traversed.

Duplantier discloses certain compounds of the formula (I) and discloses that they are useful for inhibiting PDE type IV and the production of TNF. As such, Duplantier discloses that the compounds are useful in methods for inhibiting PDE type IV and the production of TNF and, generally, that such activity is useful for treating inflammatory conditions; see, e.g., col. 3, line

43, to col. 4, line 11. Duplantier lists a variety of examples of anti-inflammatory conditions. The list includes “chronic obstructive airways disease” but also includes varied types of other diseases. No specific teachings of treating any particular disease, or a particular administration for treatment thereof, is provided by Duplantier.

Barnes teaches that tiotropium bromide administered by once-daily dry powder inhalation was more effective than ipratropium bromide in COPD patients.

Applicants respectfully submit that the rationale behind the rejection in the In re Kerkhoven decision does not apply to the instant facts. In Kerkhoven, a composition was found obvious because it was simply a matter of mixing two known and specifically disclosed compositions, both of which were taught for the same specific purpose, to provide the claimed composition also used for the same purpose. Unlike the case in Kerkhoven, the disclosure of pegsunercept in Duplantier regarding PDE IV inhibitors is much more generic and non-specific than the disclosure in Barnes regarding tiotropium bromide. Duplantier is broad and non-specific regarding the possible uses of its compounds. Duplantier primarily discloses that the compounds have activity for inhibiting PDE type IV and the production of TNF but does not suggest use of the compounds in a specific treatment. Also, there is no teaching in Duplantier of the use of its PDE IV inhibitors in an administration form which matches the powder inhalation form of Barnes. Thus, there is no support in the prior art for merely combining a composition according to Duplantier with the specific powder inhalation tiotropium bromide composition of Barnes because Duplantier discloses no particular composition for a particular use. Accordingly, the facts providing the basis for rejection in Kerkhoven, i.e., that the claims at issue are met by “mere mixing of the two [prior art] compositions,” are distinct from the facts here.

No other reason is provided for why one of ordinary skill in the art would combine the components of Duplantier and Barnes. The references themselves do not give any reasonable basis to combine a tiotropium component with the Duplantier compounds or a PDE IV inhibitor with the tiotropium bromide formulation of Barnes.

Regarding claim 20-34, an additional basis for nonobviousness is provided. Duplantier provides no suggestion of a composition of its PDE IV inhibitors in a form for inhalation administration. There is no reasoning given why one of ordinary skill in the art would provide the DE IV inhibitors in a form for inhalation administration or that there was any reasonable basis to expect they would provide their desired activity in such form. Additionally, it is even more clear that the Kerkhoven rationale does not apply to render these claims obvious. Since Duplantier neither discloses or suggests a composition suitable for inhalation administration, merely combining an embodiment of Duplantier with Barnes does not result in the claimed invention. The Office action alleges that Barnes teaches it would be obvious to administer any compounds used to treat COPD by inhalation. Applicants see no basis for such allegation. Barnes does not appear to teach inhalation of PDE IV inhibitors, particularly those taught by Duplantier.

For all of the above reasons, it is urged that the combined teachings of Duplantier and Barnes, considered as a whole, fail to render the claimed invention obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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